

RESEARCH AFFILIATION AGREEMENT

THIS RESEARCH AFFILIATION AGREEMENT (this “**Agreement**”) is entered into on this 30th day of October, 2015 (the “**Effective Date**”) by and between The Carle Foundation and its affiliates and subsidiaries, including, but not limited to The Carle Foundation Hospital and Carle Physician Group (collectively, “**Carle**”) and The Board of Trustees of the University of Illinois, acting for its Urbana-Champaign campus (“**University**”). Each party may be referred to individually as a “**Party**” and collectively as the “**Parties**.”

RECITALS

The Parties share a vision for research, innovation, and transformation, Carle and the University of Illinois at Urbana-Champaign will create a unique research partnership defined by collaboration, mutual respect, and the ultimate shared goal of transforming health care. This partnership will allow each organization to grow and prosper by leveraging respective assets and talents in a structured yet flexible research environment that supports exploration and discovery. This approach will support the independence and creativity of researchers from all disciplines, physicians and clinicians, and will encourage the free exchange of ideas and opportunities. As ideas transform into informal explorations and then into formal research projects, the governance structure will nimbly support the process by matching resources and guidance with the needs of the researchers. From exploring interesting ideas to launching formal human clinical research trials, the Research Affiliation structure provides a progressive tiered approach that recognizes the different stages, resource requirements, and development needs of the researchers;

The Parties stand on a springboard – opportunities abound for new discoveries through scientific research, technology, clinical relationships, and entrepreneurship. This Research Affiliation will provide the necessary latitude and support so together the Parties can spark innovation and create a nationally renowned research environment dedicated to improving scientific understanding of human health and applying knowledge and discoveries to improve health care for all;

The Parties’ lasting collaborative research affiliation will leverage and build upon Carle’s strengths in broad-based clinical care and translational and clinical research and the University’s strengths in biological, engineering, behavioral, physical, and computational sciences. The goals of the affiliation are to: launch and nurture a first-of-its-kind innovation ecosystem to attract researchers, scholars, providers, policymakers, and health care entities; foster groundbreaking biomedical research leading to pioneering improvements for the population’s health throughout the continuum of care (i.e., preventive medicine, chronic disease management, acute care, rehabilitative medicine, and end-of-life care); and establish Carle and the University as national leaders in the future of health care; and

Through the partnership, the Parties will develop and nurture:

- A seamless environment for collaborative research, education, inquiry-based medicine, and entrepreneurship that stimulates inquiry and creativity and fosters active interrelationships and flow of ideas and innovations among scientists, clinicians and entrepreneurs;
- Enhanced opportunities for clinical and translational research, external research funding, professional development, and medical and health science education in Champaign-Urbana;
- Increased availability for patients in central and southern Illinois of clinical and translational research trials and innovative health-care solutions that support lifelong health and wellbeing;
- Expanded opportunities for translational and entrepreneurial initiatives that expeditiously bring research findings and insights into powerful new medical technologies that improve human health; and
- Recognition of Champaign-Urbana as a destination of choice for the location of research and innovation sites by health care related entities;

NOW, THEREFORE, in consideration of the mutual covenants, promises and conditions set forth in this Agreement, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

For the purpose of this Agreement, the following terms have the meanings set forth below. Capitalized terms not set forth in this Article 1 are defined within the Agreement:

1.1 “Affiliation Agreement” means the *Affiliation Agreement By and Between The Carle Foundation and The Board of Trustees of the University of Illinois for the Carle Illinois College of Medicine*.

1.2 “Background IP” means all Intellectual Property and Intellectual Property Rights owned or controlled by a Party and existing prior to the Effective Date or arising outside of Collaborative Research that is reasonably necessary in the performance of Collaborative Research.

1.3 “Biological Material” means any and all tangible matter derived from a plant or animal including tissues, cells, cell lines, cellular extracts, fluids, proteins, and genetic materials of plants or animals including humans, and any derivative, part, progeny, and modification thereof and thereto, including synthetic nucleic acids, recombinant nucleic acids, recombinant cells, and transgenic or cloned animals.

1.4 “Carle Health Care Provider” means a physician or other health care provider who is employed by Carle. For the avoidance of doubt, a Carle Health Care Provider includes a Carle-employed resident or fellow.

1.5 “**Carle Illinois College of Medicine**” or “**CI COM**” shall have the meaning set forth in the Affiliation Agreement.

1.6 “**Collaborative Research**” or “**Collaborative Study**” means Research that involves Investigators from both Parties that commences after the Effective Date as well as those Research studies that commenced prior to the Effective Date under the Former Agreement, which is described in Section 2.1.1. A Collaborative Study “commences” upon IRB approval in the case of human subjects research. In the case of a Collaborative Study that is not human subjects research, such study “commences” when a research-initiating agreement such as a confidentiality agreement is signed or when some other research-enabling agreement, such as a material transfer or data use agreement, is signed.

1.7 “**DHHS**” means the U.S. Department of Health and Human Services.

1.8 “**FDA**” means the U.S. Food and Drug Administration.

1.9 “**Funder**” means a third party, other than a Sponsor, that provides financial or in-kind support for a Collaborative Study.

1.10 “**HIPAA**” means the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (Pub. L. No. 111-5), and their implementing regulations as amended from time to time.

1.11 “**Intellectual Property**” and “**IP**” mean all tangible and intangible conceptions, ideas, innovations, discoveries, inventions, processes, machines, formulae, formulations, compounds, compositions, equipment, improvements, enhancements, modifications, technological developments, know-how, show-how, methods, techniques, systems, designs, schematics, production systems and plans, software, documentation, data, programs and information, and works of authorship, whether or not patentable, copyrightable, or susceptible to any other form of legal protection.

1.12 “**Intellectual Property Rights**” and “**IP Rights**” mean any and all forms of intangible property rights in any jurisdiction throughout the world, including without limitation all rights to: (a) all patents, trade secrets, trademarks, trade names, copyrights, moral rights, rights of publicity, mask work rights, and all other industrial or intangible property rights throughout the world, including without limitation rights in inventions, technologies, designs, and utility models; (b) all grants and registrations worldwide in connection with any of the foregoing, and all rights with respect thereto; (c) all applications for any such grant or registration; (d) all rights of priority under international conventions to make such applications and the right to control their prosecution, and all amendments, continuations, divisions and continuations-in-part of such applications; and (e) all corrections, reissues, patents of addition, extensions, and renewals of any such grant, registration, or right.

1.13 “Inventor” means the individual or individuals who invented or discovered the subject matter of the Intellectual Property at issue.

1.14 “Investigator” means a principal investigator, co-investigator, sub-investigator, or a researcher, regardless of title, who is responsible for the design, conduct, reporting of results, or oversight of a Research Study.

1.15 “IRB” means institutional review board.

1.16 “Joint IP” means, subject to the exclusions and conditions in Article 6, any IP that is not Background IP and that is authored, invented, discovered, conceived, or developed (as determined according to U.S. IP law including copyright, trade secret and patent law, as applicable) in the performance of a Collaborative Study by both a University Investigator who is under an obligation to assign IP Rights to University and a Carle Health Care Provider who is under an obligation to assign IP Rights to Carle, or by an individual with appointments at both University and Carle and to whose compensation both University and Carle contribute.

1.17 “Net Royalties” means Royalties less (a) any unreimbursed Patent Prosecution Expenses and (b) any unreimbursed Royalty Agreement Expenses.

1.18 “OTM” means the Illinois Office of Technology Management on the Urbana Campus.

1.19 “Patent Prosecution Expenses” means all documented, out-of-pocket expenses incurred by a Party for the preparation, filing, prosecution, and maintenance of patent applications and patents arising from Joint IP.

1.20 “Patient Medical Record” means all information, in whatever form, documenting the provision of health care to a Carle patient by a Carle Health Care Provider and maintained by Carle. The Patient Medical Record may include Study Data.

1.21 “Primary Employer” has the meaning set forth in the *Hiring Guidelines* referenced in Article 7 of this Agreement.

1.22 “Research” or “Research Study” means a systematic investigation, experimentation, and/or testing for the advancement of generalizable knowledge.

1.23 “Royalty” means any payments received from exploiting any Joint IP and IP Rights thereto, including, but not limited to, sale, license issue and maintenance fees, minimum royalties, earned royalties, milestone payments, equity and the like, but shall not include payments received for reimbursement of Patent Prosecution or other Expenses.

1.24 “Royalty Agreement Expenses” means any reasonable, documented out-of-pocket expenses (exclusive of staff salaries and other fixed costs) incurred by a Party in the marketing and exploitation, either by sale, license, or otherwise of IP Rights in

Joint IP and OTM-Serviced Carle IP.

1.25 “Secondary Employer” has the meaning set forth in the *Hiring Guidelines* referenced in Article 7 of this Agreement.

1.26 “Shared Employee” means an individual who is employed by either Carle or University but who is shared with the other Party for a specified percentage of time in exchange for compensation paid by the other Party to the individual’s Primary Employer.

1.27 “Sponsor” has the meaning set forth in the FDA regulations with respect to FDA-regulated Collaborative Studies, and, for all other Collaborative Studies, means the party who designs the Collaborative Study and at whose behest it is conducted.

1.28 “Student” means a student of the University. For the avoidance of doubt, Student does not include a Carle Health Care Provider.

1.29 “Study Data” means information in whatever form, that is collected or generated in the course of a Collaborative Study, or made available as part of a clinical data Research repository, by either Carle or University or both and includes both original information and derivative information. Examples of Study Data include but is not limited to: (i) records necessary for the reconstruction and evaluation of Collaborative Research; (ii) data contained in laboratory notebooks; and (iii) case report forms and source documentation for human subjects Collaborative Research.

1.30 “Test Technology” means a drug, biologic, device, or technique that is the subject of a Collaborative Study.

1.31 “University Investigator” means any Investigator who is employed solely by the University.

ARTICLE 2

ESTABLISHMENT OF RESEARCH AFFILIATION AND DESIGNATING COLLABORATIVE STUDIES

2.1 Intent of the Parties. It is the intent of the Parties to establish a more robust relationship and collaboration with respect to the conduct of Research in a way that leverages the Parties’ respective strengths. Specifically, the Parties wish to grow their respective Research programs, facilitate the design and conduct of Research, and accelerate the delivery of innovative diagnostics and therapeutics critical to patients through Collaborative Research. In this regard, the Parties are committed to working together, in good faith, to establish and maintain a robust and compliant research environment that attracts and retains outstanding researchers and other Research professionals; maximizes access to external research funding; and supports the development and conduct of innovative Collaborative Studies.

2.1.1 This Agreement supersedes the Research Affiliation Agreement between the Parties that was effective on January 15, 2010 ("**Former Agreement**"), except as otherwise specified in Section 2.2

2.2 Designation of Collaborative Research or Collaborative Studies. A Research Study meeting the definition of a Collaborative Study constitutes a Collaborative Study without any further action by the Parties and will be subject to provisions of this Agreement applicable to Collaborative Studies. Collaborative Research that commenced prior to the Effective Date shall be governed by this Agreement and any relevant agreements pertaining to the Research and not by the Former Agreement, unless otherwise agreed upon by both, of the Parties. Notwithstanding anything in this Agreement to the contrary, and taking into consideration the input of the Strategic Affiliation Steering Committee, the Parties may agree in writing to designate as a Collaborative Study a Research Study that would otherwise not constitute a Collaborative Study under this Agreement.

2.3 Clinical Data Registry/Biorepository. The Parties are committed to exploring the feasibility of a collaborative clinical data Research registry and Biological Material biorepository. If the Parties determine that a clinical data Research registry and/or Biological Material biorepository would be of mutual interest and benefit to them, the Parties will negotiate in good faith an agreement on infrastructure, management and costs.

ARTICLE 3 GOVERNANCE

3.1 Strategic Affiliation Steering Committee.

3.1.1 Governance. To guide the strategic vision of the Parties' research partnership with a focus on opportunities with mutual interest and benefit to them, the Parties shall establish a Strategic Affiliation Steering Committee. The Strategic Affiliation Steering Committee ("Steering Committee") shall have the following responsibilities:

(a) Make recommendations to appropriate leadership of each Party for high-level decisions on matters requiring a significant allocation of resources or investment in infrastructure;

(b) Review and recommend implementation of new programs/initiatives, or modifications to existing programs/initiatives;

(c) Recommend, review and approve strategic plans including, but not limited to, goals and strategies for collaborative translational research and entrepreneurial activities;

(d) Serve as a forum for the Parties to discuss goals and strategy for the development and conduct of Collaborative Studies;

(e) Identify opportunities for investment in Collaborative Studies (e.g., determine the availability and allocation of seed funding opportunities);

(f) Assist the Parties with the identification and proactive resolution, to the extent appropriate, of conflicts between the Parties and/or individual Investigators;

(g) Assist with dispute resolution as described in Article 12;
and

(h) Perform such other responsibilities as may be agreed by the Parties from time to time.

3.1.2 Composition. The Steering Committee shall consist of eight (8) members, four (4) voting representatives appointed by University and four (4) voting representatives appointed by Carle. The members of the Steering Committee shall include (i) the University Vice Chancellor for Research (“**University VCR**”), (ii) the Carle Chief Medical Officer (“**CMO**”), (iii) Carle's Vice-President of Research (“**Carle VPR**”), and (iv) the Director of the University’s Interdisciplinary Health Sciences Initiative (“**IHSI**”). The CMO shall have the authority to appoint the remaining Carle members. Likewise, the University VCR, in consultation with the Provost, shall have the authority to appoint the remaining University members. As appropriate, each of the Parties also may invite other individuals to attend meetings of the Steering Committee as non-voting advisors, provided that such invitees are subject to the confidentiality obligations of this Agreement set forth in Article 8.

3.1.3 Committee Chair. For the first two (2) years of this Agreement, the CMO shall serve as the Steering Committee chair. Before expiration of the CMO's two (2)-year term, and every two (2) years thereafter, the Steering Committee voting representatives shall elect a chair. The chair shall be responsible for setting meeting dates and conducting meetings.

3.1.4 Meetings. The Steering Committee should endeavor to meet semi-annually and may meet as frequently as it deems appropriate. Carle shall staff the meetings for the benefit of the Parties, unless otherwise agreed to by the Parties.

3.1.5 Action. Any formal decision or recommendation of the Steering Committee shall require a simple majority vote of the members present at a duly convened meeting at which a quorum exists, including the affirmative vote of at least two (2) Carle members and at least two (2) University members. The Steering Committee has the authority to amend, modify or waive compliance with this Agreement, by a supermajority vote of the members (*i.e.* the affirmative vote of six (6)) members including at least three (3) Carle members and at least three (3) University members.

3.1.6 Special Committees. The Steering Committee may designate one (1) or more additional committees, each of which shall consist of two (2) or more members, including at least one (1) Carle member and one (1) University member and

such other persons as the Steering Committee shall designate.

3.2 Research Innovation Committee.

3.2.1 Governance. To assist with the implementation of this Agreement and the strategic vision of the partnership, the Parties shall establish a Research Innovation Committee to serve in an advisory capacity. For the avoidance of doubt, the Research Innovation Committee shall not have the authority to amend, modify or waive compliance with this Agreement. The Research Innovation Committee shall have the following responsibilities:

- (a)** Serve as a forum for the Parties to encourage, promote and monitor the progress of Collaborative Studies;
- (b)** Periodically review the conduct of Collaborative Studies, including but not limited to status of invoicing for Carle and/or University funded studies;
- (c)** Plan and recommend allocation of resources to Collaborative Studies, taking into consideration budgetary and Payor Coverage Analysis activity and needs;
- (d)** Identify emerging opportunities for improvement, expansion and growth and present such opportunities to the Steering Committee for consideration;
- (e)** Manage funding and sponsorship opportunities approved by the Steering Committee and identify a clear path for processing requests for resources from representatives of the Parties;
- (f)** Identify opportunities for the involvement of Students in Collaborative Studies and other activities to be conducted under this Agreement;
- (g)** Explore opportunities for research, grant proposal, and commercialization/entrepreneurial training opportunities;
- (h)** Facilitate professional interactions to bring representatives from both Parties together, including but not limited to seminars, conferences, educational opportunities, etc.;
- (i)** Assist with coordination of the Parties' activities and schedules under this Agreement, including, as needed, the identification, formation and decommissioning of subcommittees to work on particular objectives;
- (j)** Provide feedback to researchers on contracting decisions in which a third party is involved in research funding;

(k) Make recommendations on exploitation of Joint IP, as appropriate, and elevate concerns to the Steering Committee as needed; and

(l) Perform such other responsibilities as recommended by the Steering Committee from time to time.

3.2.2 Composition. The Research Innovation Committee shall consist of six (6) members, three (3) voting representatives appointed by the University VCR and three (3) voting representatives appointed by Carle CMO, in consultation with the Steering Committee. As appropriate, each of the Parties also may invite other individuals to attend meetings of the Research Innovation Committee as non-voting advisors, provided that such invitees are subject to the confidentiality obligations of this Agreement set forth in Article 8.

3.2.3 Chair. For the first two (2) years of this Agreement, the IHSI Director shall serve as Chair. Before expiration of the IHSI Director's two (2)-year term, and every two (2) years thereafter, the Research Innovation Committee shall elect a Chair.

3.2.4 Meetings. Unless otherwise determined by the Research Innovation Committee, the Research Innovation Committee shall meet quarterly, and more frequently if it deems appropriate. The University shall staff the meetings for the benefit of the Parties, unless otherwise agreed to by the Parties.

3.2.5 Action. The Research Innovation Committee generally shall function as a forum for discussion. Where the Steering Committee formally requests the Research Innovation Committee to make a formal decision or recommendation, the action of the Research Innovation Committee shall require the affirmative vote of a simple majority of the members.

3.3 Interaction with College of Medicine Governance

3.3.1 There shall be no formal reporting structure between the Joint Liaison Committee under the CI COM Affiliation Agreement and either the Steering Committee or the Research Innovation Committee, although individuals may be appointed to serve on more than one (1) of these committees.

3.3.2 The three (3) committees referenced in Section 3.3.1 shall hold an annual retreat to foster an understanding and awareness of their strategic goals and respective approaches by sharing ideas and plans that could benefit collaborations at the CI COM and University levels. The Chair of the Joint Liaison Committee shall be responsible for scheduling the retreat each year.

ARTICLE 4 CONDUCT OF COLLABORATIVE STUDIES

4.1 Conduct of Collaborative Studies. The Parties shall conduct Collaborative Studies in accordance with this Agreement and applicable law, regulations, guidance, standards, assurances, and other requirements. The Parties acknowledge that Collaborative Studies require different levels of engagement depending on the nature of the Research, Investigator time commitment and the resources available to the Investigators. The level of engagement for Collaborative Research thus may range from an informal exchange of ideas, Biological Material, or Study Data to a significant engagement in which both Parties, and potentially third parties, collaborate on long-term projects involving large investments of time and resources. Accordingly, the level of engagement for a Collaborative Study will fall into one (1) of five (5) “**Tiers**” described in Exhibit A hereto. Exhibit A sets forth the general characteristics of each Tier of engagement. The Tiers are not intended to be prescriptive or limiting but, rather, are intended to provide a shared framework for expectations of the Parties and their Investigators.

4.2 Future Opportunities. If a Tier 2, 3 or 4 Collaborative Study involving human subjects gives rise to opportunities for either Party to participate in subsequent, follow-on studies, the Party presented with such opportunity shall use reasonable best efforts to discuss with the Funder or Sponsor the possibility of conducting such subsequent, follow-on study/studies as a Collaborative Study.

4.3 Conflict of Interest in Research. The Parties recognize that each Party has respective compliance obligations and institutional areas of priority with respect to conflicts of interest. Accordingly, each Party shall be responsible for identifying and evaluating individual, imputed and institutional conflicts of interest, and if applicable, developing conflict management plans, as outlined in their respective policies and procedures. In each instance in which a Party determines that a conflict of interest exists in connection with a Collaborative Study, the Party shall provide a copy of the applicable conflict of interest management plan to the other Party, and, where both Parties have determined that a conflict of interest exist, the Parties shall collaborate on a joint conflict of interest management plan.

4.3.1 For the avoidance of doubt, both Parties must conclude that all conflicts of interest can be adequately managed for the Collaborative Study to proceed.

4.3.2 Carle may also independently evaluate conflict of interest issues that pertain to clinical care at Carle-owned or operated facilities, and, as appropriate, shall communicate with University about such conflict of interest issues that impact or may impact Collaborative Studies.

4.4 IRB Review. The Parties agree to pursue process development for the streamlining of IRB review to ensure that the respective compliance considerations and efficiency needs of each Party are met. The over-arching goal of the adopted IRB process will be to allow for expeditious and compliant review of research activities in the progression of strategic initiatives.

ARTICLE 5

COMPLIANCE AND APPLICABLE POLICIES AND PROCEDURES

5.1 Compliance Generally. Each Party, in its performance of this Agreement, shall comply with all applicable federal, state, and local law and professional standards. All standards set forth in this Agreement are minimum requirements. If a Party determines that this Agreement may create a material risk of violating any legal requirement, then the Party shall give written notice to the other, and the Parties shall use good faith efforts to amend the Agreement as necessary to achieve compliance. If such amendment is not possible, then the Parties shall cooperate to terminate this Agreement as soon as practicable with due consideration to human subject safety and Research matters.

5.2 HIPAA and Human Subject Protection. Each Party shall comply with all applicable federal and state laws and regulations relating to patient privacy and the protection of human subjects in Research, including HIPAA and the Common Rule.

5.3 Stark/Anti-Kickback. The Parties intend that this Agreement and the activities performed by them pursuant to it will comply with the federal program anti-kickback statute, 42 U.S.C. § 1320a-7b, and the the federal Ethics in Patient Referrals law, 42 U.S.C. § 1395nn, together with their companion regulations.

5.4 Suspension, Debarment, and Exclusion. Each Party represents that, to the best of its knowledge, neither it nor any of its employees or agents performing Collaborative Research under this Agreement is suspended, debarred, or excluded from participating in any federal or state financial or nonfinancial assistance or health care program. If a Party becomes aware that this representation is no longer correct, then it shall notify the other Party no later than three (3) business days after becoming aware of a suspension, debarment or exclusion.

5.5 Licensing and Accreditation. Each Party shall maintain all requisite licenses and accreditations to fulfill its obligations under this Agreement.

5.6 Animal Research. Each Party shall comply with all applicable federal and state laws, regulations, policies, and guidelines relating to the conduct of animal research, including but not limited to the Animal Welfare Act and, insofar as the Parties conduct animal research supported by the U.S. Public Health Service (“PHS”), the PHS Policy (together, the “**Animal Research Requirements**”). Without limiting the generality of the foregoing, University shall submit all reports and maintain all assurances, registrations, accreditations and approvals required under the Animal Research Requirements to conduct animal research as contemplated under this Agreement.

5.7 Family Education and Privacy Act of 1974. Each Party acknowledges that certain information about Students may be confidential by law, including the Family and Educational Rights and Privacy Act of 1974 (“**FERPA**”), 20 U.S.C. §1232g. Each Party shall protect such information in accordance with the law.

5.8 Anti-Terrorist Compliance. Each Party certifies its compliance with all laws restricting or prohibiting U.S. persons from engaging in transactions and dealings with countries, entities, or individuals subject to economic sanctions administered by the U.S. Department of the Treasury's Office of Foreign Assets Control.

5.9 Non-Discrimination/Human Rights. Each Party certifies that it will comply with all applicable provisions of the Illinois Human Rights Act, together with all companion rules and regulations in performance of this Agreement.

5.10 Drug-Free Workplace. Each Party certifies that it will comply with applicable provisions of the Illinois Drug Free Workplace Act.

5.11 Discriminatory Club Dues. No Party will pay any dues or fees on behalf of its employees or agents, or subsidize or otherwise reimburse them; for payment of their dues or fees, to any discriminatory club.

5.12 Equal Opportunity. Each Party, in its performance of this Agreement, will comply with all relevant provisions of the Equal Opportunity Employment Clause at 44111. Adm. Code 750, Appendix A.

5.13 Tax-Exemption. Nothing in this Agreement is intended to jeopardize the tax-exempt status of either Party. In particular, no Party shall endorse, or be expected to endorse, the products or services offered by the other Party.

5.14 Access to Books and Records. To the extent that University provides services to Carle that are payable by a federal healthcare program, University shall make available to the Comptroller General of the United States, the Department of Health and Human Services and their duly authorized representatives, for four (4) years after the latest furnishing of services pursuant to this Agreement, access to the books, documents and records and such other information as may be required by the Comptroller General or Secretary of DHHS to verify the nature and extent of the costs of services provided by University.

5.15 Audits.

5.15.1 Unless prohibited by applicable law, a Party shall promptly notify the other Party if the notifying Party is the subject of an audit, review, inspection or investigation by a regulatory authority or governmental agency in connection with Collaborative Studies. In the event of an audit, review, inspection or investigation, each Party shall make appropriate documents available to the other Party upon request and in a timely manner. The Parties shall share the results of the findings as appropriate.

5.15.2 Where a Collaborative Study requires monitoring under applicable law, regulation or governmental guidance, including but not limited to 21 C.F.R § 312 and 21 C.F.R § 812, the Parties shall comply with monitoring by the Sponsor. If a Party is a Sponsor, such Party recognizes its obligations to perform monitoring (or arrange for monitoring by a qualified designee) and to maintain records consistent with applicable law.

5.16 Research Compliance Training. In addition to any existing Research training obligations set forth in their respective policies and procedures, the Parties shall work together to develop supplemental training to assist Investigators and other Research Study team members to comply with this Agreement. The Parties shall make their respective training materials and training records generated pursuant to this Section 5.16 available to one another, where possible. Carle shall provide required and other appropriate training and orientation for University personnel who are considered members of Carle's Workforce, as such term is defined in HIPAA, while performing activities under this Agreement, and University shall provide required and other appropriate training and orientation (e.g., animal care and use; laboratory safety; biosafety; and radiation and radioactive materials safety) for Carle personnel who will be engaged in activities relating to the conduct of Collaborative Studies.

5.17 Applicable Policies and Procedures. Collaborative Studies shall be governed by the respective policies and procedures of each Party, and each proposed Collaborative Study must be approved by each Party in accordance with its respective policies and procedures.

5.18 Enforcement of Policies. Each Party shall have authority to enforce its respective policies and procedures with respect to individuals, whether or not employed by the Party, subject to such policies and procedures.

ARTICLE 6

INTELLECTUAL PROPERTY

6.1 Intellectual Property Ownership and Rights and Obligations; Generally.

6.1.1 Ownership of IP. Title to IP conceived or reduced to practice solely by University employees or agents shall vest in the University ("**University IP**"). Title to IP conceived or reduced to practice solely by Carle employees or agents shall vest in Carle ("**Carle IP**"). Title to IP conceived or reduced to practice jointly by Carle employees or agents and University employees or agents shall vest in both Parties ("**Joint IP**"). Rights, including exploitation and enforcement rights, to Joint IP shall be subject to the terms of this Article 6.

6.1.2 Control of Patient Medical Records. Joint IP does not include Patient Medical Records. Subject to applicable law or regulation, Carle shall have exclusive control of Patient Medical Records.

6.1.3 Ownership of Study Data. Except as otherwise required by law, Funders and/or Sponsors, the Parties shall jointly own Study Data and act in partnership to ensure Study Data remains mutually and readily accessible for the intended purposes. Each Party and its Investigators shall be accountable for the stewardship of Study Data, including its proper and secure management and retention, in order to fulfill the Parties' obligations to each other and to Sponsors, Funders and research oversight authorities. As a general rule, the Party whose Investigator collects the Study Data shall be responsible for its maintenance, security and retention on behalf of both Parties. The Parties shall enter into data use agreements as necessary to document their rights and obligations with

respect to their use of Study Data, as well as those of any third parties who may be granted access to or use of Study Data.

6.1.4 Biological Material Exclusion. Joint IP does not include Biological Material either supplied or collected for a Collaborative Study. Subject to applicable contracts, law and regulations concerning ownership and control of Biological Material, (a) Biological Material that is supplied by or through Carle or collected at Carle for a Collaborative Study shall be owned or controlled by Carle and (b) Biological Material that is supplied by or through University for a Collaborative Study shall be owned or controlled by University. The Parties shall enter into material transfer agreements as necessary to document their rights and obligations with respect to their use of Biological Material, as well as those rights and obligations of any third parties who might receive Biological Material for Research.

6.1.5 Assignment of IP. Carle shall require each of its employees and agents who participate in a Collaborative Study to assign to Carle in writing all of his/her IP Rights arising from the Collaborative Study. University shall require, through its *General Rules Concerning University Organization and Procedure* or otherwise, each of its employees and agents who participate in a Collaborative Study to assign to University in writing all of his/her IP Rights arising from the Collaborative Study. The Parties shall cooperate in securing IP Rights from any person who is not an employee or agent of a Party but who desires to participate in a Collaborative Study and who may be expected to generate IP.

6.1.6 Preemption by Third-Party Agreements. Where a Collaborative Study is funded by a third-party, to the extent there is a conflict between the terms of the relevant third-party funding contract and this Agreement, the IP Rights arising from the Collaborative Study will be governed by the terms of the relevant third-party funding contract.

6.1.7 Disclosure Requirements. Each Party shall require any of its employees and agents who participate in a Collaborative Study to promptly disclose to the OTM, in a form or format reasonably required by OTM, all Joint IP that has the potential to be brought into practical use for public benefit. The Parties shall also require their employees or agents to keep confidential such Joint IP for at least a time sufficient to allow the Parties to determine whether to seek IP Rights to the Joint IP. OTM shall disclose to Carle any Carle IP and Joint IP disclosed to OTM, and shall inform Carle of any University IP resulting from Carle funding. The University shall hold in the strictest confidence all disclosures of Carle IP.

6.1.8 Background IP. Each Party shall identify Background IP that may be required in a Collaborative Study and shall grant the other Party research use rights for such identified Background IP. Nothing in this Agreement grants to either Party any rights or interest in the other Party's Background IP. Each Party shall retain ownership and control of its Background IP. Neither Party acquires any rights under this Agreement to the other Party's Background IP other than the non-exclusive, limited license to practice Background IP in the performance of a Collaborative Study.

6.1.9 Joint IP; License. University hereby grants to Carle a fully paid up, non-exclusive, worldwide, irrevocable, perpetual, limited license to any IP Rights in University IP for use in another Collaborative Study. Carle hereby grants to University a fully paid up, non-exclusive, worldwide, irrevocable, perpetual limited license to any IP Rights in Carle IP for use in another Collaborative Study.

6.1.10 Representations and Disclaimers. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, TO THE FULLEST EXTENT PERMITTED BY LAW, UNIVERSITY AND CARLE DISCLAIM ALL EXPRESS OR IMPLIED CONDITIONS, REPRESENTATIONS AND WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT, WITH RESPECT TO BACKGROUND IP, JOINT IP, CARLE IP AND UNIVERSITY IP AND RIGHTS THERETO.

6.2 Intellectual Property Management; Prosecution; Expenses.

6.2.1 Inventorship Determination. In the case of Joint IP, on an invention-by-invention basis, OTM shall recommend to Carle whether to pursue IP Rights, and the Parties shall cooperate in good faith to determine the actions to be taken and to establish the Inventors in accordance with U.S. patent law and the Inventors' relative inventive contributions to the Joint IP.

6.2.2 Institutional Share. The Parties shall share royalties and expenses on Joint IP in the same proportions as the inventive contributions of each Party's Inventors ("**Institutional Share**"); provided, however, that if an Inventor is a Shared Employee, the contribution and Institutional share shall be determined by considering both the Shared Employee's percentage of inventive contribution and percentage of appointment to each Party. *See examples set forth at **Exhibit B**.*

6.2.3 OTM-Serviced Carle IP. Carle may request of University in writing the use of OTM's administrative services to evaluate, market or license Carle IP Rights according to OTM's standard processes ("**OTM-Serviced Carle IP**"). Costs for such administration services may be charged by University on either a fixed fee or revenue-sharing basis, depending on the nature of the services provided, and will be agreed by the Parties in advance of services commencing. Carle shall be solely responsible for determining how to proceed with protecting and licensing Carle IP. Carle may discontinue OTM's management services for OTM-Serviced Carle IP at any time by providing thirty (30) days' advance written notice to University. Carle shall pay for services provided through the date of termination and for all costs associated with non-cancelable obligations entered into prior to University's receipt of notice. Upon termination of the OTM management services, University shall provide Carle with copies of all materials relevant to such Carle IP, including, but not limited to, information relevant to the filing, prosecution and maintenance of the Carle IP Rights and licensing agreements.

6.2.4 Prosecution of Patent Rights. The University, through its OTM, shall file, prosecute, and maintain patent applications and patents arising from either Joint

IP or from OTM-Serviced Carle IP (collectively “**OTM-Serviced IP**”). OTM shall consult with Carle regarding whether and where to seek IP Rights for any OTM-Serviced IP and the process of obtaining, managing and maintaining any IP Rights for any OTM-Serviced IP. All patent applications filed and patents issued from Joint IP shall be made in the name of both Parties. All patent applications filed and patents issued from OTM-Serviced Carle IP shall be made in the name of Carle or its designate. In the case of OTM-Serviced Carle IP, University shall advise patent counsel that Carle is the client represented and that patent counsel shall bill Carle directly for legal services provided. University shall instruct patent counsel to provide Carle with all serial numbers and filing dates, as well as copies of patent applications, office actions and other correspondence that University or its patent counsel receives from the U.S. Patent and Trademark Office (“USPTO”), or corresponding foreign patent registration office, with respect to such patent applications and patents, and to provide Carle with copies of all of proposed filings with the USPTO, or corresponding foreign patent registration office, with respect to such patent applications and patents, including copies of all issued patents. University shall use best efforts to provide copies of the above material to Carle promptly so that Carle shall have an opportunity to comment thereon and have its comments considered.

6.2.5 University IP. In the case of University IP, University shall be solely responsible for decisions regarding pursuit of IP Rights.

6.2.6 Abandonment. University shall not abandon the prosecution of any patent application (except in favor of a continuation application) or abandon maintenance of an issued patent arising from OTM-Serviced IP without notifying Carle in writing at least sixty (60) days in advance of any applicable deadline and allowing Carle the opportunity to prosecute such patent application or maintain such patent pursuant to Section 6.2.10.

6.2.7 Cooperation. Carle shall reasonably cooperate regarding patent filing, prosecution, and maintenance of patent applications and patents arising under OTM-Serviced IP by promptly executing such documents as University may reasonably request. Each Party shall bear its own costs in connection with its cooperation with the other Party.

6.2.8 Expenses for OTM-Serviced Carle IP. Carle shall bear the Patent Prosecution Expenses and Royalty Agreement Expenses for OTM-Serviced Carle IP. If University anticipates any extraordinary expenses arising from the preparation, filing, or prosecution of such patent applications or patents from OTM-Serviced Carle IP, University shall inform Carle and discuss a mutually acceptable course of action prior to incurring such expenses. Either monthly or quarterly, at University’s election, University shall invoice Carle for Royalty Agreement Expenses and any Patent Prosecution Expenses incurred by University in connection with OTM-Serviced Carle IP not billed directly to Carle by patent counsel. Carle shall pay the amount due no later than thirty (30) days after the invoice date. All overdue amounts shall be subject to interest of 1.5% per month (or the maximum allow permitted by law if less) of the delinquent amount.

6.2.9 Patent Prosecution Expenses for Joint IP; Invoicing. Either

monthly or quarterly, at University's election, University shall invoice Carle for Carle's share of Joint IP Patent Prosecution Expenses not paid directly or reimbursed by licensees. If University anticipates any extraordinary expenses arising from the preparation, filing, or prosecution of such patent applications or patents from Joint IP, University shall inform Carle and discuss a mutually acceptable course of action prior to incurring such expenses. Carle shall pay the amount due no later than thirty (30) days after the invoice date. Carle shall pay interest on overdue amounts. All overdue amounts shall be subject to interest of 1.5% per month (or the maximum allowed permitted by law if less) of the delinquent amount.

6.2.10 Option IP Rights. If a Party elects not to support its share of Patent Prosecution Expenses associated with certain IP Rights in a particular jurisdiction for a particular Joint IP ("**Option IP Rights**"), such Party shall notify the other Party in writing of such election and in advance of incurring additional Patent Prosecution Expenses. The Party that elects to forego the Option IP Rights shall thereafter not be responsible for additional Patent Prosecution Expenses and shall thereby relinquish any right to receive Royalties resulting from such patent filings in the particular jurisdiction for which Option IP Rights were relinquished. In such event, the Party electing to proceed with the Option IP Rights shall share Net Royalties with the inventors in accordance with Section 6.3.5.

6.3 Exploitation of Intellectual Property.

6.3.1 Authority. Carle and University shall cooperate in good faith to exploit, either by license, or otherwise, Joint IP. OTM shall take the lead, in consultation with Carle, to negotiate, execute and administer agreements to exploit Joint IP. During negotiation of a potential agreement to exploit Joint IP, OTM shall notify Carle promptly of such an agreement and its material terms and shall provide Carle an opportunity to comment thereon and have its comments fully considered by OTM. OTM shall have authority and responsibility to execute agreements exploiting Joint IP in accordance with University policy; provided, however, that Carle must approve in writing any final agreement to exploit Joint IP. At Carle's request, OTM shall take the lead, in consultation with Carle, to negotiate agreements to exploit OTM-Serviced Carle IP. Carle shall have complete authority and responsibility to execute and administer agreements exploiting Carle IP, including OTM-Serviced Carle IP. For avoidance of doubt, OTM shall not sign or administer agreements exploiting Carle IP. Where University has elected to forego the Option IP Rights and Carle has agreed to assume, at its sole expense, such Option IP Rights as described in Section 6.2.10, Carle shall have complete authority and responsibility to negotiate, execute and administer agreements exploiting the Option IP Rights.

6.3.2 Standards. University shall use all commercially reasonable efforts to license the IP Rights on OTM-Serviced IP in furtherance of the public interest. The mere failure of University to consummate a licensing arrangement shall not be deemed a breach of University's obligations under this Agreement. If Carle becomes aware of a licensing opportunity for OTM-Serviced IP, Carle shall notify University of such opportunity.

6.3.3 Reserved Rights. Notwithstanding any other provisions of this Agreement, Carle and University each expressly reserves the right to make, use, and practice the subject matter of Joint IP for its internally administered programs of teaching, research and public service. Neither Party shall exercise its respective rights to grant any licenses of Joint IP except in accordance with this Agreement.

6.3.4 Communications. University shall promptly provide Carle with copies of all term sheets and all signed license and option agreements and all related extensions and amendments on OTM-Serviced IP. University shall be responsible for administering all such license and option agreements to the mutual benefit of the Parties and shall keep Carle informed of licensee progress.

6.3.5 Distribution Generally. University shall distribute Net Royalties owed to Carle semi-annually, within sixty (60) days after January 1 and July 1 for Royalties paid during the applicable preceding six (6)-month period. With each distribution, University shall provide Carle a financial accounting showing Royalties received during the period, Patent Prosecution Expenses, any reimbursements by licensees, Royalty Agreement Expenses, and the share of Net Royalties owed Carle. In the case of third party reimbursement of Patent Prosecution Expenses already paid by the Parties, each Party shall be reimbursed its prorata share. Each Party shall be solely responsible for distributing to its respective Inventors their shares of Net Royalties in accordance with the Party's royalty-sharing policies.

6.3.6 Distribution of Royalties from Joint IP. For Joint IP, University shall pay Carle the Carle Institutional Share of Net Royalties and shall account for any previous payments by Carle or reimbursements received from third parties for Patent Prosecution Expenses.

6.3.7 Distribution of Royalties from OTM-Serviced Carle IP. For OTM-Serviced Carle IP, University shall pay to Carle one-hundred percent (100%) of Net Royalties less an administrative or service fee as set forth in Exhibit C.

6.3.8 Survival of Royalties. The respective rights of Carle, the University and Inventors to Net Royalties from the exploitation of any Joint IP or IP Rights thereto shall survive termination of this Agreement.

6.3.9 Audits. Each Party may, at its own expense and no more than once per year, audit the other Party's records relating to Joint IP, including Patent Prosecution Expense records, exploitation agreements and records relating to expenses, fees and Royalties from the exploitation of any Joint IP or IP Rights thereto.

6.4 Enforcement.

6.4.1 Notification. If a Party becomes aware of any actual, threatened or suspected infringement, or any actual or threatened allegation of invalidity of any IP Rights arising from OTM-Serviced IP within or outside the United States, it shall promptly notify the other Party in writing.

6.4.2 Defense of Rights: Joint IP. In the case of Joint IP that has not been licensed and IP Rights thereto, the Parties shall cooperatively decide, on a case-by-case basis, whether and in what manner to enforce the rights of the Parties, whether by appropriate legal proceeding or otherwise, including without limitation the settlement or abandonment of any claim either Party may have against any third party; which Party shall take the lead on enforcing or defending any such IP Rights; and the sharing of costs related to any agreed upon enforcement action, subject to any agreement relating to the exploitation of such IP Rights. Each Party shall have the right to independent counsel at its own expense. Any sums received with respect to any such action shall be applied first to reimburse out-of-pocket expenses incurred by Carle and University relating to the enforcement action, and the remaining sums shall be deemed Royalties and shall be shared by the Parties as set forth in Section 6.2.2. In any infringement suit initiated to enforce the Parties' IP Rights pursuant to this Agreement, the Parties shall, at the request and expense of the Party initiating such suit, cooperate in all reasonable respects and, to the extent possible, have their respective employees testify when reasonably requested and make available relevant records, papers, information, and Distribution of Royalties.

6.4.3 Defense of Rights: OTM-Serviced Carle IP. Carle shall determine, in its sole discretion, the manner and whether to enforce or defend any IP Rights in OTM-Serviced Carle IP.

6.5 IP Consultation and Training. The Parties shall collaborate on a program of awareness training for both physicians and faculty to promote entrepreneurial activities and to foster opportunities for translating IP to the commercial sector, such as: (i) opportunities for consultation by OTM (ii) proof-of-concept funding opportunities; (iii) venture funding via Illinois Ventures; (iv) assistance in applying for SBIR/STTR funding; (v) access to the Entrepreneurs in Residence Program at the Research Park; (vi) access for entrepreneurs to professional development; (vii) access to EnterpriseWorks programs and services; (viii) inclusion of Carle representation on the OTM Advisory Committee, scientific advisory groups, and entrepreneurship startup input related to medical technologies, as appropriate.

ARTICLE 7 SHARED EMPLOYEES

The Parties may share employees as needed in accordance with their *Hiring Guidelines*, which establish the framework for the Parties' recruitment, hiring, retention and termination of Shared Employees. The *Hiring Guidelines* must be approved by both Parties through their designated administrators and may be amended from time to time as they deem necessary. For the University, the *Hiring Guidelines* must be approved by appropriate representatives of the Office of the Provost. For Carle, the *Hiring Guidelines* must be approved by Human Resources in consultation with Legal Services.

ARTICLE 8 CONFIDENTIALITY AND PUBLICATION

8.1 Confidentiality. Each Party shall hold in confidence all proprietary information received from the other Party in connection with Collaborative Research that, if disclosed, would cause the other Party competitive harm (“**Confidential Information**”); provided, however, that each Party may share Confidential Information with third parties as required by law and to the extent necessary to perform the Collaborative Research under terms consistent with this Agreement. For written disclosure permitted hereunder, the Party disclosing Confidential Information shall mark the information “Confidential” and the time of disclosure. For oral or visual disclosures permitted hereunder, the Party disclosing the Confidential Information shall designate the information “Confidential” at the time of disclosure and confirm such designation in writing to the other Party no later than thirty (30) days after disclosure. The obligations under this Section 8.1 do not apply to any information (a) that is now or hereafter becomes part of the public domain by means other than in violation of this Agreement; (b) that the receiving Party and its employees or agents can prove by clear and convincing documented evidence was in their possession prior to the Effective Date of this Agreement, or can prove by clear and convincing documented evidence was developed without access to or use of Confidential Information; or (c) that is hereafter disclosed to the receiving Party or its employees or agents by a third party having no obligation of confidentiality with respect to such information.

8.2 Response to Information Requests. If University receives a request under the Illinois Freedom of Information Act or a request by legal process to disclose Confidential Information, University shall use reasonable efforts to provide prompt notice to Carle and shall reasonably cooperate with Carle to protect any Carle Confidential Information to the extent permitted by law.

8.3 Publications.

8.3.1 Review Period. Researchers from either Party may publish or publicly disclose non-confidential Collaborative Research results without interference from the other Party after providing the other Party a thirty (30)-day period for review and comment. Upon written notice by the reviewing Party that the proposed publication contains Confidential Information or enabling disclosures of IP of the reviewing Party, the Party wishing to publish or publicly disclose will either revise the publication to eliminate such disclosures, or will delay publication for a limited period in its discretion to allow for preparation and filing of U.S. patent applications and deletion of Confidential Information of the reviewing Party. The Parties shall cooperate so that Student theses or dissertations are not adversely affected by any delay.

8.3.2 Acknowledgement. Each Party shall acknowledge the contributions of the other Party in publications or public presentations as scientifically appropriate.

ARTICLE 9

RETENTION OF AUTHORITY

9.1 Access to Premises. Each Party may deny access to its facilities to any person who it deems to be a risk to himself or herself or to patients, or who does not meet the safety, health, or professional standards of the Party. If Carle denies access to a University Faculty Member, employee, or Student, then within two (2) business days of denying access to the person, Carle must notify the University IHSI Director and the Office of the Provost of the denial. If University denies access to a Carle employee, then within two (2) business days of denying access to the person, University must notify the Carle VPR, of the denial. To the extent permitted by law, the Party denying access shall provide to the other Party all relevant information requested by the non-denying Party and shall cooperate in the non-denying Party's investigation, if any. Each Party may determine whether to take action against the person so denied access in accordance with the denying Party's policies, including the individual's right to a hearing and/or appeal.

9.2 No Agency. Unless otherwise expressly agreed in writing, neither Party shall represent or purport to represent the other Party in any matter or make any commitments of any kind on behalf of the other Party.

ARTICLE 10

TERM AND TERMINATION

10.1 Term of Agreement. This Agreement shall be effective on the Effective Date and continue perpetually unless terminated in accordance with Section 10.2 (the "Term").

10.2 Termination.

10.2.1 A Party may terminate this Agreement without cause upon one hundred eighty (180) days' prior written notice to the non-terminating Party.

10.2.2 This Agreement may be terminated by either Party upon ninety (90) days prior written notice if the other Party breaches any material provision of this Agreement and either the breach cannot be cured to the reasonable satisfaction of the non-breaching Party or, if the breach can be cured, it is not cured by the breaching Party to the reasonable satisfaction to the non-breaching Party within the ninety (90) day notice period; provided, however, that such termination shall not be effective until the Parties have completed the dispute resolution process set forth in Article 12.

10.2.3 This Agreement may be terminated by either Party upon ninety (90) days' prior written notice if the other Party: (1) becomes insolvent, (2) is generally unable to pay, or fails to pay, its debts as they become due, (3) files, or has filed against it, a petition for voluntary or involuntary bankruptcy or pursuant to any other insolvency law, (4) makes or seeks to make a general assignment for the benefit of its creditors, or (5) applies for, or consents to, the appointment of a trustee, receiver, or custodian for a substantial part of its property or business.

10.2.4 Either Party may terminate this Agreement immediately if it reasonably believes that such termination is necessary to protect the safety of human subjects; provided, however, that immediate termination pursuant to this Section 10.2.4 may not occur if such risks to human subjects can be equally remediated by terminating one or more specific Collaborative Studies.

10.2.5 If either Party is suspended, debarred or excluded from participation, or otherwise becomes ineligible to participate in any federal or state financial or nonfinancial assistance or healthcare program during the term of this Agreement, such Party will notify the other Party in writing no later than three (3) business days after such action. Whether or not such a notice is given, the other Party may immediately terminate this Agreement effective on the effective date of the exclusion, suspension, debarment or ineligibility.

10.3 Termination of a Collaborative Study.

10.3.1 Either Party may terminate a Tier 2, 3, or 4 Collaborative Study only in accordance with applicable law and by providing ninety (90) days' prior advance written notice to the other Party. Termination of a Tier 3 or 4 Collaborative Study as a result of a dispute shall not be effective until each Investigator consults with the Carle VPR or University VCR, as the case may be, so that they can understand and assess the reasons for the dispute and afford a final opportunity for resolution short of termination. The final opportunity for resolution shall occur within the ninety (90) day notice period.

10.3.2 If either Party notifies the other Party pursuant to Section 5.4 that an employee or agent performing Collaborative Research is suspended, debarred or excluded from participation, or otherwise becomes ineligible to participate, in any federal or state financial or nonfinancial assistance or healthcare program during the term of this Agreement, the Parties shall cooperate to either remove the employee or agent from participation in the Collaborative Research or, alternatively, promptly terminate the Collaborative Research as they determine necessary to meet their legal obligations.

10.4 Effect of Termination of a Collaborative Study. Upon either providing or receiving notice of termination of a Collaborative Study, the Parties shall, as applicable: (a) immediately stop enrolling human subjects in the Collaborative Study, if applicable, (b) to the extent medically permissible, as determined by one or both of the Parties in the exercise of medical judgment and by the overseeing IRB, cease administering the Test Technology and conducting procedures on enrolled human subjects; and (c) provide notices to regulatory authorities and government agencies and take any other actions required under applicable law. If one (1) or more Collaborative Studies terminate, the Parties will notify the applicable Funders and Sponsors and will, in the case of Collaborative Studies involving human subjects, work with the supervising IRB to provide appropriate notice to the human subjects. By agreement of the Parties and the Funder or Sponsor, the Parties may continue to collaborate on a Collaborative Study that is terminated by operation of the termination of the Agreement if the Parties enter into a separate, written agreement to govern the former Collaborative Study.

10.5 Effect of Termination Generally. Termination of this Agreement shall terminate all active Collaborative Studies; provided, however, that the Parties shall work together to conclude any active Collaborative Studies in a productive, constructive and efficient manner, in accordance with the process set forth in Section 10.3 of this Agreement.

10.6 Non-Appropriation. Notwithstanding anything to the contrary in this Agreement, if, in any fiscal year ending June 30, the Illinois General Assembly, the Governor, or any State funding source fails to appropriate or otherwise make available funds for any program authorized under this Agreement, the University shall promptly notify Carle and may terminate the affected program without penalty and without further obligation to Carle if University deems termination necessary.

ARTICLE 11 INDEMNIFICATION AND INSURANCE

11.1 Indemnification.

11.1.1 Carle, at its sole cost and expense, will defend, indemnify and hold University and University's trustees, directors, officers, employees, agents, representatives and designees, in their official and personal capacities (collectively "**University Indemnified**"), harmless from and against any and all claims, demands, suits, damages, judgments, liabilities, losses and expenses, including without limitation personal or bodily injury to or death of any person, defamation, infringement of copyright, trademark, patent or other intellectual property, and reasonable attorneys' fees and expenses of litigation (collectively, "**University Liabilities**"), to which University Indemnified may become subject actually or allegedly arising out of, relating to or resulting from the negligence of: (1) Carle's trustees, directors, officers, employees, volunteers, agents, representatives and designees while acting within the scope of their duties and pursuant to this Agreement; and (2) Students, faculty and staff of C-I COM when those Students, faculty and staff are under the direct supervision and control of Carle, its employees or agents and are acting pursuant to this Agreement; except to the extent that University Liabilities arise out of, or result from the misconduct or negligence of University Indemnified. Carle shall name University as an additional insured on appropriate Carle insurance policies solely for the purpose of effectuating this contractual indemnification. This indemnification shall survive expiration or termination of this Agreement.

11.1.2 To the extent permitted by law, University, at its sole cost and expense, shall defend, indemnify and hold Carle, and Carle's trustees, directors, officers, employees, agents, representatives and designees, in their official and personal capacities (collectively "**Carle Indemnified**"), harmless from and against any and all claims, demands, suits, damages, judgments, liabilities, losses and expenses, including without limitation personal or bodily injury to or death of any person, defamation, and reasonable attorneys' fees and expenses of litigation (collectively, "**Carle Liabilities**"), to which Carle Indemnified may become subject actually or allegedly arising out of, relating to or resulting from the negligence of: (1) University' trustees, directors, officers, employees,

volunteers, agents, representatives and designees while acting within the scope of their duties and pursuant to this Agreement; and (2) Students, faculty and staff of C-I COM when those Students, faculty and staff are under the direct supervision and control of University, its employees or agents and acting pursuant to this Agreement; except to the extent that Carle Liabilities arise out of, or result from the misconduct or negligence of Carle Indemnified. University shall name Carle as an additional insured on appropriate University insurance policies solely for the purpose of effectuating this contractual indemnification. This indemnification shall survive expiration or termination of this Agreement.

11.1.3 Neither Party makes any commitment to pay liabilities in excess of the balances made available under its insurance plan.

11.1.4 In cases involving penalties, fines and other liabilities not covered by insurance, and where the Parties may be subject to joint and several liability, neither Party shall seek to prosecute claims for contribution or indemnity against the other or the other's insureds. Subject to the approval of their respective insurance carriers, if such approval is necessary, each Party will apportion any such liability based on the relative fault of the Parties. If agreement cannot be reached, then the Parties shall resolve all apportionment issues by advisory arbitration. The arbitrator shall be an attorney appointed by the Parties. If the Parties cannot agree on a single arbitrator, they shall exchange names of two qualified arbitrators. Each Party shall strike one name. If more than one name remains in the pool, then the arbitrator shall be chosen by a blind draw. The Parties intend for the arbitrator to conduct the proceeding as informally and as expeditiously as possible and in a manner that is fair and open to the Parties. The proceedings may contemplate submission of written and oral presentations and consultation with witnesses. The decision shall be in writing and contain the reasons underlying the apportionment. At the arbitrator's discretion, the proceedings may be conducted in whole or in part as provided for in the Uniform Arbitration Act, 710 ILCS 5. Each party shall share equally in the arbitration costs.

11.1.5 For the avoidance of doubt, in the case of a Shared Employee, the Primary Employer and not the Secondary Employer shall be liable for the acts and omissions of the employee, except as provided in Section 11.2.6 below.

11.2 Insurance.

11.2.1 The Parties shall appoint their respective risk management administrators (each a **"Risk Manager"** and collectively **"Risk Managers"**) to serve as liaisons to each other regarding management issues. The Risk Managers shall inform each other of any claim and any lawsuit which is threatened, or any event that causes or contributes to injury or death, and could result in a lawsuit, that arises from or in connection with this Agreement. The Parties shall cooperate with each other and either Carle or University shall adjust claims actually or allegedly arising out of or relating to this Agreement.

11.2.2 The Parties shall cooperate with each other, and either Carle or University, or both, shall provide for the defense of litigation actually or allegedly arising

out of or relating to this Agreement. The Parties, through their respective legal counsel shall execute joint defense agreements as may be appropriate from time to time.

11.2.3 The Parties' respective business personal property, including furnishings and equipment that may at any time be at or in the other Party's facilities, shall be kept at each owning Party's sole risk, cost, and expense and identified with appropriate property labels. Except as expressly provided otherwise herein, neither Party shall be liable to the other Party or to any other person or entity for loss or damage to the other Party's real property, business property or interruption to a Party's business. Property shall be insured on a replacement cost basis, insuring against "special" causes of loss perils.

11.2.4 University has and agrees to maintain a program of insurance and/or self-insurance ("**University Insurance Program**") under which it indemnifies and defends its trustees, officers, employees, agents and Students ("**University Insureds**") from any and all liabilities, judgments, costs, expenses and attorney's fees that arise out of and in the course of their University responsibilities. Nothing in this Agreement shall be construed as precluding the University from modifying the terms, conditions, or coverages of the University Insurance Program. University shall provide Carle with ninety (90) days' prior written notice of any material alteration in the terms, conditions and coverages of the University Insurance Program.

11.2.5 Carle has and agrees to maintain a program of insurance and/or self-insurance ("**Carle's Insurance Program**") under which it indemnifies and defends its directors, officers, employees and agents ("**Carle Insureds**") from any and all liabilities, judgments, costs, expenses and attorney's fees that arise out of and in the course of performing their Carle responsibilities. Nothing in this Agreement shall be construed as precluding Carle from modifying the terms, conditions, or coverages of Carle's Insurance Program. Carle shall provide University with ninety (90) days' prior written notice of any material alteration in the terms, conditions, and coverages of Carle's Insurance Program.

11.2.6 Physicians and other licensed medical providers performing clinical activities at Carle shall be Carle Insureds, not University Insureds, even if they are primarily employed by University. Each physician or other licensed medical provider employed by University performing clinical activities at locations other than Carle, shall be either an University Insured or covered by the program of insurance and/or self-insurance maintained by the location where such physician or licensed medical provider is performing clinical services. Residents, while employed by and/or assigned to Carle, shall be Carle Insureds and not University Insureds. Students shall at all times be University Insureds and not Carle Insureds.

11.2.7 The Parties acknowledge that the Illinois Court of Claims has exclusive jurisdiction to hear contract and tort claims against University and that nothing in this Agreement is intended by University to waive jurisdiction or the protections of the Illinois Court of Claims Act or the State Lawsuit Immunity Act.

11.2.8 Both Parties shall conform to any new and existing federal

and/or state legislation that have reporting requirements including but not limited to the Illinois Medical Practice Act, the Healthcare Quality Improvement Act, and Medicare, Medicaid, and the SCHIP Extension Act.

11.2.9 Each Party shall each maintain or self-insure the following types of insurance at its own cost and expense, and which shall include at a minimum the following:

(a) Directors' and officers' liability insurance for its respective directors, trustees and officers, in amounts not less than Two Million Dollars (\$2,000,000) per claim/occurrence and Six Million Dollars (\$6,000,000) annual aggregate;

(b) Workers' compensation insurance at the State of Illinois statutory limit and including a waiver of subrogation;

(c) Employer's liability insurance in an amount not less than One Million Dollars (\$1,000,000);

(d) Medical malpractice insurance in amounts not less than One Million Dollars (\$1,000,000) per claim/occurrence and Three Million Dollars (\$3,000,000) annual aggregate for its own respective insureds, as specified in Section 11.2.6;

(e) Commercial general liability insurance in an amount not less than Two Million Dollars (\$2,000,000) per claim/occurrence and Four Million Dollars (\$4,000,000) annual aggregate, or such greater amount as determined by the Parties' respective Risk Managers to be necessary, appropriate and commercially reasonable;

(f) Business auto liability insurance in an amount not less than One Million Dollars (\$1,000,000) per claim/occurrence, including owned, non-owned and hired vehicles and providing both bodily injury and property damage coverage;

(g) Umbrella excess liability insurance over the commercial general liability, auto liability and employer's liability insurance in an amount not less than Five Million Dollars (\$5,000,000) per claim/occurrence and Five Million Dollars (\$5,000,000) annual aggregate, or such greater amount as determined by the Parties' respective Risk Managers to be necessary, appropriate and commercially reasonable;

(h) Crime and fidelity insurance in an amount not less than One Million Dollars (\$1,000,000);

(i) Property insurance in amounts as determined by the Parties' respective Risk Managers to be necessary, appropriate and commercially reasonable; and

(j) Cyber technology liability insurance in an amount not less

than Ten Million Dollars (\$10,000,000) per claim/occurrence and Ten Million Dollars (\$10,000,000) aggregate.

11.2.10 The Parties shall provide each other, upon request, with certificates of insurance evidencing the insurance and shall provide updated certificates as the insurance policies renew or are otherwise modified. The Parties shall be responsible for all costs and expenses associated with their own respective insurance, including any deductibles and retention.

ARTICLE 12 DISPUTE RESOLUTION

12.1 Dispute Resolution Mechanism. The Parties shall resolve any dispute arising out of or relating to this Agreement (each a “**Dispute**”) in accordance with this Article 12.

12.2 Dispute Resolution Process. The Parties shall attempt in good faith, by informal or formal discussions, to promptly resolve all Disputes not resolved in the regular course of business, including disagreement between them with respect to the relationship between the Parties, any provision of this Agreement, and defaults or claims of default.

12.2.1 Any Dispute that cannot be resolved during the normal course of business shall be brought to the attention of the University VCR and Carle VPR for resolution. Subject to any applicable privilege, all facts and documentation pertinent to the Dispute shall be made available promptly by each Party to the other.

12.2.2 This informal process shall be expedited and not exceed sixty-five (65) days from the date the University VCR and Carle VPR receive notice of the Dispute (“**Informal Process Period**”), unless they each agree to extend this period.

12.2.3 If the Dispute is not resolved during the initial thirty (30) days of the Informal Process Period and the Steering Committee has not yet been consulted regarding the Dispute, the Dispute then shall be brought to the Steering Committee for advice and consultation. The Steering Committee shall explore potential solutions to the Dispute and present these to the University VCR and Carle VPR within thirty (30) days of being consulted.

12.2.4 At the end of the Informal Process Period, if the Dispute remains unresolved following referral to the Steering Committee, the matter shall be brought to the attention of the Provost and the CMO. If the dispute remains unresolved following referral to the Provost and the CMO, the Parties may elect to participate in voluntary third-party mediation, the Parties shall agree on a mediator within seven (7) days of (i) the Steering Committee's presentation of potential solutions, or (ii) the conclusion of the Informal Process Period, whichever is later. If the Parties are unable to agree on a mediator within seven (7) days, the mediator shall be selected in accordance with the alternative dispute resolution process established by the American Health Lawyers Association. The mediator shall have no authority to impose a resolution but shall work

with the Parties to reach a mutually acceptable solution. The Parties shall give the mediator their full cooperation and shall participate in all sessions convened by the mediator. The cost of mediation shall be borne equally by the Parties.

12.2.5 Following mediation, if any, either Party may take the following actions regarding any Dispute that is not fully resolved to its reasonable satisfaction: (1) proceed to termination; (2) seek judicial resolution of the Dispute in a court of competent jurisdiction; or (3) maintain the status quo.

ARTICLE 13 GENERAL MATTERS

13.1 Notice. In order to be effective, any notice, demand, or request from one Party to another must be given in writing to the affected Party by either hand delivery or by certified mail, postage prepaid and return receipt requested, to the addresses set forth below or to such other address designated by a party in accordance with this provision. Notices shall be effective upon receipt.

UNIVERSITY: University of Illinois at Urbana-Champaign
Office of Sponsored Programs
1901 S. First Street, Suite A
Champaign, IL 61820
Attn: Director

CARLE: Carle Foundation Hospital
611 W. Park St.
Urbana, IL 61801
Attn: President/Chief Executive Officer

13.2 Governing Law; Claims Against University. This Agreement shall be governed by and construed in accordance with the laws of the State of Illinois without reference to its conflict of law provisions. Claims against the University shall be filed in accordance with the Illinois Court of Claims Act.

13.3 Third Party Beneficiaries. This Agreement does not create any rights, or rights of enforcement, in third parties.

13.4 Merger/Amendment. This document, with all exhibits, constitutes the entire understanding of the Parties relating to the subject matter of this Agreement. Any changes in to the terms of this Agreement shall be valid only if made by written amendment signed by each Party.

13.5 No Assignment. Neither Party may assign any of its rights or obligations under this Agreement, either in part or in whole, without the prior written consent of the other Party.

13.6 Relationship of the Parties. The Parties do not intend for this Agreement to create an agency, joint venture, joint employment or partnership relationship. Nothing in this Agreement is intended to authorize a Party to act as agent for another.

13.7 Entire Agreement. This document, together with its attachments, embodies the entire understanding of the Parties with respect to its subject matter and shall supersede all previous or contemporaneous communications, either verbal or written, between the Parties relating to the subject matter.

13.8 Resolution of Disputes. The Parties shall resolve any disputes in accordance with the process set forth in Article 12 of this Agreement.

13.9 No Waiver. A Party's failure to enforce any right under this Agreement shall not constitute a waiver of that Party's subsequent right of enforcement.

13.10 Financial Records. Each Party shall maintain all financial and administration records related to this Agreement for a minimum of ten (10) years after the termination of the Agreement, and shall make all such records available to the other Party and its designated agents, for inspection and copying upon reasonable notice and during normal business hours. For the avoidance of doubt, records relating to the conduct of specific Collaborative Studies shall be maintained for the longer of ten (10) years after the completion of the Collaborative Study, the retention period required by applicable law, or the retention period set forth in a Party's policies and procedures.

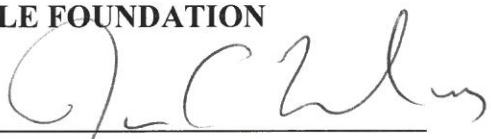
13.11 Additional Opportunities for Collaboration or Affiliation. Each Party shall use reasonable efforts to make available to the other Party as appropriate collaboration and affiliation opportunities in an effort to further the aims set forth in Section 2.1. To that end, the Parties, through Carle's CMO and the University's Provost and/or VCR, agree to confer and consult with one another as early in the evaluation process as possible when new opportunities for collaboration or affiliation arise that may be mutually beneficial to both Parties or when one of the Parties is contemplating a Research relationship of the nature set forth in Section 2.1 with a third party.

13.12 Survival. The following provisions shall survive termination of this Agreement: 5.14, 5.15.1, 6.1--6.4.3, 8, 11.1, 11.2.1, 11.2.2, 11.2.6, 11.2.7, 13.1, 13.2, 13.5, 13.6, 13.10, and 13.12.

13.13 Severability. If any provision of this Agreement is held invalid, the remainder of the Agreement shall continue in effect to the extent possible.

Each Party has caused its authorized signatory to sign this Agreement on the date indicated below.

THE CARLE FOUNDATION

By: 
Name: James C. Leonard, M.D.
Title: President and Chief Executive Officer

Date: 10-26-2015

THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS

By:  Date: 10-26-15
Name: Walter K. Knorr
Title: Comptroller

Campus Approvals:

 Date: 10-26-15
Peter E. Schiffer
Vice Chancellor for Research

 Date: 10-28-15
Edward Feser
Interim Provost and Vice Chancellor for Academic Affairs

Exhibit A: Scope of Engagement – Tiers 0-4

This chart shows the general characteristics of the various levels of Research engagement by the Parties and their Investigators. The Tiers are not intended to be prescriptive or limiting in any way but, rather, are intended to provide a shared framework for expectations of the Parties and their Investigators.

Tier	Level of Autonomy (Description)	Investigator Relationship	Joint Grant Development	Funding	Joint Publication	Level of Governance / Committee Facilitation	Resource Allocation	Example
0	Brief exchanges of ideas, purchase of services, and/or minimal non-human samples	Formal or informal interactions with no commitment	Not expected	No funding	Not expected	None	None	University Investigator contacting a Carle Provider to advise or consult on a Research Study
1	Purchased services relationship for access to data, samples and/or tissues without significant intellectual collaboration	Formal interactions to explain and understand accessed materials. No commitment otherwise. Requires Materials Transfer Agreement.	Not expected	External and/or one Party funding	Not expected	Research Innovation Committee ("RIC") facilitation if promising results will lead to collaborative future studies	Purchase of services or supplies	Small data set, owned by Carle, to be studied by a University Investigator or chemical analysis requested by a Carle Investigator for a Carle study
2	Significant time commitments required in the provision of large data samples and/or intellectual collaboration	Formal interactions and collaboration around the use of materials and/or intellectual capital Dissolution of relationship requires 90 days written notice.	Not expected	External and/or potential for funding by both Parties	Recognition in publication	RIC facilitation	In-kind services at the discretion of research leadership	Carle Provider utilizing research materials created by University investigator for new project idea. Provision of large data set that requires Carle physician expertise and resources to identify appropriate sample for inclusion in study
3	Substantial collaboration with resources committed by one or both parties.	Formal interactions and collaboration in the performance and completion of the Research with agreed protocols/statements of work. Dissolution of relationship requires administrative consultation/mediation with University VCR and Carle VPR and 90 days written notice.	Joint grant-writing	External and/or potential for funding by both Parties	Co-authorship based on publication and authorship standards	RIC facilitation	Funding available upon recommendation by Steering Committee. Application and selection process managed by RIC	Carle Provider and a University Investigator engaged in a larger multi-investigator project utilizing internal seed funding

	Extended collaboration involving a program of Research. Specifications of the relationship to be detailed in an MOU	Formal interactions in the performance and completion of Research which requires an agreement detailing roles, responsibilities, and expectations of each Party. Dissolution of relationship requires administrative consultation/mediation with University VCR and Carle VPR and 90 days written notice.	Joint grant-writing	External and/or potential for funding by both Parties	Co-authorship based on publication and authorship standards	RJC facilitation	Funding available upon recommendation by Steering Committee. Application and selection process managed by RJC recommendation	Development of a major initiative involving multiple investigators from both Parties and potential external partners that requires significant investment of time and resources.
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Exhibit B

Example 1:

Joint IP is invented by Inventor 1 and Inventor 2 where

- Inventor 1's inventive contribution is 50%
- Inventor 2's inventive contribution is 50%
- Inventor 1 has a 100% University appointment
- Inventor 2 has a 100% Carle appointment

The University's Institutional Share is 50% and Carle's Institutional Share is 50% as shown below:

	Inventive Contribution	University Percentage Appointment	Carle Percentage Appointment	University Institutional Share	Carle Institutional Share
Inventor 1	50%	100%	0%	$50\% \times 100\% = 50\%$	$50\% \times 0\% = 0\%$
Inventor 2	50%	0%	100%	$50\% \times 0\% = 0\%$	$50\% \times 100\% = 50\%$
Total				50%	50%

Example 2:

Joint IP is invented by Inventor 1 and Inventor 2 where

- Inventor 1's inventive contribution is 50%
- Inventor 2's inventive contribution is 50%
- Inventor 1 has an 80% University appointment and 20% Carle appointment
- Inventor 2 has a 100% Carle appointment.

The University's Institutional Share is 40% and Carle's Institutional Share is 60% as shown below:

	Inventive Contribution	University Percentage Appointment	Carle Percentage Appointment	University Institutional Share	Carle Institutional Share
Inventor 1	50%	80%	20%	$50\% \times 80\% = 40\%$	$50\% \times 20\% = 10\%$
Inventor 2	50%	0%	100%	$50\% \times 0\% = 0\%$	$50\% \times 100\% = 50\%$
Total				40%	60%

Example 3:

Joint IP is invented by Inventor 1 and Inventor 2 and Inventor 3 where

- Inventor 1's inventive contribution is 20%
- Inventor 2's inventive contribution is 30%
- Inventor 3's inventive contribution is 50%
- Inventor 1 has an 80% University appointment and 20% Carle appointment
- Inventor 2 has an 50% University appointment and 50% Carle appointment
- Inventor 3 has an 20% University appointment and 80% Carle appointment

The University's Institutional Share is 41% and Carle's Institutional Share is 59% as shown below:

	Inventive Contribution	University Percentage Appointment	Carle Percentage Appointment	University Institutional Share	Carle Institutional Share
Inventor 1	20%	80%	20%	$20\% \times 80\% = 16\%$	$20\% \times 20\% = 4\%$
Inventor 2	30%	50%	50%	$30\% \times 50\% = 15\%$	$30\% \times 50\% = 15\%$
Inventor 3	50%	20%	80%	$50\% \times 20\% = 10\%$	$50\% \times 80\% = 40\%$
Total				41%	59%

Example 4

In general, when Joint IP is invented by N inventors where

- Inventor n's inventive contribution is $X_n\%$
- Inventor n has a $Y_n\%$ University appointment and $Z_n\%$ Carle appointment

the University's Institutional share will be

$$X_1\% \times Y_1\% + X_2\% \times Y_2\% + X_3\% \times Y_3\% + \dots$$

$X_N\% \times Y_N\%$

and Carle's Institutional share will be

$$X_1\% \times Z_1\% + X_2\% \times Z_2\% + X_3\% \times Z_3\% + \dots X_N\% \times Z_N\%$$